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EXAMINER

LAU, JONATHAN S

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/530,126	Applicant(s) HELIN ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-96 and 98-116 is/are pending in the application.
- 4a) Of the above claim(s) 96, 101 and 106-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94, 95, 98-100 and 102-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 24 June 2008, in which claims 94 is amended, claim 102 is amended to change the scope and breadth of the claim, and claim 97 is canceled.

This application is the national stage entry of PCT/FI03/00734, filed 06 Oct 2003; and claims benefit of foreign priority document FINLAND 20021772, filed 04 Oct 2002. This foreign priority document is in English.

Claims 94-96 and 98-116 are pending in the current application. Claims 106-116, drawn to non-elected inventions, are withdrawn. Claims 96 and 101, drawn to non-elected species, are withdrawn.

Election/Restrictions

Applicant notes that the citation of Tibor Mora et al. can be interpreted as reactions of single molecular species with multiple alternatives, e.g. D-glucose used exclusively to produce poly-D-glucose, D-galactose used exclusively to produce poly-D-galactose, implicitly excluding the reaction of D-glucose with any saccharide other than D-glucose, such as D-galactose. However Tibor Mora et al. discloses the condensation of a mixture of saccharides at column 1, lines 55-60.

Therefore the Restriction Requirement was properly made FINAL.

Objections Withdrawn

Applicant's Amendment, filed 24 June 2008, with respect to objections to claim 102 has been fully considered and is persuasive, as amended claim 102 does not recited the identified informality.

This objection has been **withdrawn**.

Applicant's Amendment, filed 24 June 2008, with respect to objections to claim 97 as being a substantial duplicate of claim 94 has been fully considered and is persuasive, as claim 97 is canceled.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment, filed 24 June 2008, with respect to claim 102 rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement has been fully considered and is persuasive, as amended claim 102 defines the anhydro product such that the ordinary definition in the art of an anhydro saccharide, eg. a pyranose or furanose ring, is not encompassed by the term.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 24 June 2008, with respect to claims 102 rejected under 35 USC 112, second paragraph, as being indefinite has been fully considered and is persuasive, as amended claim 102 does not recite a "minimum" amount.

This rejection has been **withdrawn**.

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Applicant's Remarks, filed 24 June 2008, with respect to claims 94, 95, 97, 98, 100, 103, 104 and 105 rejected under 35 U.S.C. 102(b) as being anticipated by Hindsgaul et al. (WIPO publication WO 96/06102, published 29 Feb 1996, provided by Applicant in IDS filed 04 Apr 2005) has been fully considered and is persuasive, as Hindsgaul et al. discloses the reaction of a C1-activated, C2-C6-protected saccharide with a non-protected saccharide, or core structure (page 8, paragraph 4 and compound (1) at top of page 13). The method of coupling the C1-activated, C2-C6-protected saccharide to an unprotected or partially protected saccharide, or core structure, does not anticipate the instant method because the C1-activated, C2-C6-protected saccharide that is added to said core structure is not a non-protected saccharide.

However, Applicant's Remarks that a C1 activating group constitutes a protecting group are not persuasive. The definition in the art of a protected group is "Temporary chemical transformation of a reactive group into a group that does not react under conditions where the non-protected group reacts." (definition of protection of a reactive group, IUPAC Gold Book, cited in PTO-892). An activating group at the C1 position does not transform the reactive C1 position into a group that does not react under conditions where the non-transformed group reacts, therefore an activating group is not a protecting group and a saccharide bearing a C1 activating group is non-protected at the C1 position because it is activated so that it does react rather than protected so that it does not react.

This rejection has been **withdrawn**.

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Applicant's Remarks, filed 24 June 2008, with respect to claims 94 and 99 rejected under 35 U.S.C. 103(a) as being unpatentable over Hindsgaul et al. (WIPO publication WO 96/06102, published 29 Feb 1996, provided by Applicant in IDS filed 04 Apr 2005) in view of Rennhard (US Patent 3,766,165, issued 16 Oct 1973, of record) has been fully considered and is persuasive, as Hindsgaul et al. discloses the reaction of a C1-activated, C2-C6-protected saccharide with a non-protected saccharide, or core structure (page 8, paragraph 4 and compound (1) at top of page 13). The method of coupling the C1-activated, C2-C6-protected saccharide to an unprotected or partially protected saccharide, or core structure, does not make obvious the instant method because the C1-activated, C2-C6-protected saccharide that is added to said core structure is not a non-protected saccharide.

However, Applicant's Remarks that a C1 activating group constitutes a protecting group are not persuasive. The definition in the art of a protected group is "Temporary chemical transformation of a reactive group into a group that does not react under conditions where the non-protected group reacts." (definition of protection of a reactive group, IUPAC Gold Book, cited in PTO-892). An activating group at the C1 position does not transform the reactive C1 position into a group that does not react under conditions where the non-transformed group reacts, therefore an activating group is not a protecting group and a saccharide bearing a C1 activating group is non-protected at the C1 position because it is activated so that it does react rather than protected so that it does not react.

This rejection has been **withdrawn**.

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The following are new ground(s) of rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 94, 95, 98-100 and 102-105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making those glycoconjugates having a well-known utility, does not reasonably provide enablement for the scope of the glycoconjugates made by said method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the products made by the instant invention commensurate in scope with these claims. Absent a well-known, or specific and substantial utility, one of skill in the art would not know how to use the products made by the scope of the instant method.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for the preparation of glycoconjugates comprising reacting under condensing conditions involving acid or metal catalysis at least two non-protected saccharides in order to form a glycosidic bond between said saccharides through any free hydroxyl group position in said saccharides. The method is also drawn to the method of preparation wherein the oligosaccharides produced form a library of oligosaccharides (instant claims 103-105).

The Breadth of the claims: The scope of the claims is infinite. Any possible chemical structure could potentially be used as the glycoconjugate made by the instant method.

The state of the prior art: Kanie et al. (Solid Support Oligosaccharide Synthesis and Combinatorial Carbohydrate Libraries, 2001, p239-256, cited in PTO-892) discloses carbohydrates have the potential to become an important class of pharmaceuticals, and are useful in the high-throughput screen to discover pharmaceutical leads (page 239, paragraph 1). Kanie et al. discloses “the basic strategy of a library approach is to synthesize large sets of molecules at a time, even as complex mixtures, and then determine whether any of the compounds is inhibitory. The active compound must be subsequently identified.” (emphasis added) (page 239, paragraph 2). Kanie et al. discloses the combinatorial number of trisaccharides possibly formed using nine carbohydrates is 119,736. (page 241, paragraph 3). Kanie et al. discloses examples wherein a combinatorial library of elements shown to be acceptors for fucosyltransferases can produce a carbohydrate that does not function as an acceptor for the enzyme (page 247, paragraph 1). Kanie et al. discloses further developments

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are needed in order to identify the structures of active carbohydrate (page 254, paragraph CONCLUSIONS).

St. Hilaire et al. (Angew. Chem. Int. Ed, 2000, 39, p1162-1179, cited in PTO-892) discloses the biological activity of carbohydrate ligands is structure dependent and complicated by a range of factors (page 1164, right column, paragraph 1). St. Hilaire et al. discloses an example wherein protein binding to simple mannose oligosaccharide is relatively weak and activation of a complement cascade is only effected when the protein interacts with large polymannans (page 1164, right column, paragraph 3). St. Hilaire et al. discloses oligosaccharide libraries as a screening tool for drug discovery, and that screening of such mixtures is nontrivial in terms of experimental methodologies (page 1175, left column, paragraph 5 and right column, paragraph 1). St. Hilaire et al. discloses an example in which the screening of a carbohydrate library found no carbohydrate-based inhibitors (page 1175, right column, paragraph 2). St. Hilaire et al. discloses the technology for the identification of active oligosaccharides isolated from a library has been developed but only to a certain extent, and that synthesis and analysis of larger solution-phase libraries are not practical due to complexity and lengthy nature (page 1176, right column, paragraph Conclusions).

Specific polysaccharides are generally recognized as safe (GRAS) by the U.S. Food and Drug Administration for use as food additives or pharmaceutical excipients. For example food starches, dextrans having an average molecular weight less than 100,000, and dextrin are categorized as GRAS as food additives (EAFUS: A Food Additive Database, cited in PTO-892). However, the scope of the glycoconjugates made by the instant method encompasses glycoconjugates that are not known to be

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generally recognized as safe to be administered as food additives or pharmaceutical excipients.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The reactivities of the different hydroxyl groups of a saccharide are unpredictable. Kanie et al. discloses the results of performing glycosylation reactions on totally unprotected acceptor to create a random mixture of saccharides could hardly have been anticipated because of this unpredictable reactivity (page 245, paragraph 1). Further, the sheer number of possible glycoconjugates means that one skilled in the art cannot predict whether the glycoconjugates made by said method will be a glycoconjugate with a known use. Therefore the claimed invention is unpredictable because one skilled in the art cannot predict how to use the glycoconjugates made by said method.

The amount of direction or guidance presented: The specification speaks generally about carbohydrates present in biology, such as galactose structures present in mammalian glycobiology and galactose epitopes known as pathogen receptors (paragraph 201) xylose epitopes present rarely on mammalian biology and more commonly in various plant materials (paragraph 202), and products resemble natural polylactosamines used as acceptors for glycosyltransferase modifying lactose and/lactosamines (paragraph 327), and that pathogens such as *Helicobacter pylori* or intestinal pathogenic viruses and bacteria in gastrointestinal tract bind to glycoconjugates (paragraph 204). It is suggested that said carbohydrate polymers and oligomers are useful in pharmaceutical and food industries (paragraph 1). However, guidance is not given for what specific compounds may have a utility specific to said

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compound, rather than the general utility of the broad class of carbohydrate polymers and oligomers in pharmaceutical and food industries or the well known utility of specific oligosaccharides designated as GRAS.

The presence or absence of working examples: No working examples are provided. Reference is made to products that resemble natural polylactosaminens which have reported to be excellent in representation of bioactive oligosaccharide epitopes (paragraph 327).

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as possible glycoconjugate structures. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible glycoconjugates beyond those with a use that is well known in the art, (such as natural polylactosamines) one skilled in the art would undertake a novel and extensive research program to synthesize large sets of molecules at a time, even as complex mixtures, determine whether any of the compounds is active or safe and then subsequently identify the compound. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of glycoconjugates, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

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Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for all possible glycoconjugates because absent a well-known, or specific and substantial utility, one of skill in the art would not know how to use the scope of products made by the instant method.

Amended Claim 98 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some temperatures less than 180°C, for example at room temperature, 80°C, 150-160°C, and 50°C at paragraphs 369-373 of the corresponding PGPub, does not reasonably provide enablement for all temperatures less than 180°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for the preparation of glycoconjugates comprising reacting under condensing conditions involving acid or metal catalysis at

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least two non-protected saccharides in order to form a glycosidic bond between said saccharides through any free hydroxyl group position in said saccharides.

The state of the prior art: Kanie et al. (Solid Support Oligosaccharide Synthesis and Combinatorial Carbohydrate Libraries, 2001, p239-256, cited in PTO-892) discloses the condensation method wherein the donor molecule has protecting groups at C2-C6 and an activating group at the C1 position using $\text{BF}_3\text{-OEt}_2$, a Lewis acid catalyst, at room temperature (page 245, figure 12.6).

Rennhard (US Patent 3,766,165, issued 16 Oct 1973, of record) discloses the condensation method wherein the reaction preferably occurs at from about 140°C to about 180°C (column 5, lines 5-10).

Tibor Mora et al. (US Patent 2,719,179, issued 27 Sep 1955, of record) discloses the condensation of a saccharide in the presence of acid catalysis at a temperatures of -78.5°C (example I at column 3 lines 70-75), 80 to 100°C (example II at column 4, lines 25-30), 92 to 96°C (example III at column 5, lines 1-5), below 40°C (example IV at column 5, lines 70-75), and room temperature (example V at column 7, lines 45-50).

It is well known in the art that no chemical reactions occur at absolute zero, -273.15°C , because no molecular motion occurs at that temperature.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While the reactivity of most chemical functionalities is relatively predictable, the sheer number of reaction conditions and reagent concentrations means that one skilled in the art cannot predict the usefulness for all possible reaction temperatures. Therefore the claimed invention is unpredictable.

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The Breadth of the claims: The scope of the claims is broad. Any temperature less than 180°C is encompassed by the claims. The claims encompass the temperature absolute zero, -273.15°C.

The amount of direction or guidance presented: The specification speaks generally about reactions at above 80°C or 140°C at paragraph 120, and 1 degree of Celsius to 50 degrees of Celsius at paragraph 244 of the corresponding PGPub. However, guidance is not given for a lower limit for the temperature at which the reaction is envisioned.

The presence or absence of working examples: The only working examples provided are for the reaction at room temperature, 80°C, 150-160°C, and 50°C at paragraphs 369-373 of the corresponding PGPub.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as chemical synthesis. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible temperatures beyond those known in the art, (such as -78.5°C, room temperature, or 140°C to 180°C) one skilled in the art would undertake a novel and extensive research program to establish the lower limit for the temperature at all reaction conditions. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of synthetic reactions, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for all possible temperatures lower than 180°C.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claims 99 and 102-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 99, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are required of the claimed invention. See MPEP § 2173.05(d).

The term "bitter taste" in claim 102 is a relative term which renders the claim indefinite. The specification does not provide a standard for ascertaining the requisite degree to judge the subjective observation of taste, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is well known that there is genetic variation in the ability to taste a bitter substance. Therefore "bitter taste" is a relative term due to the subjectivity of the taster.

The term "undesired color" in claim 102 is a relative term which renders the claim indefinite. The term "undesired color" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. No criteria are provided to judge whether a color is "undesired" or what colors are considered

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“undesired”. For example the same color red may be desired in a candy but undesired in pure cane sugar. Therefore “undesired color” is a term relative to undefined criteria for judging desirability of a color.

There is insufficient antecedent basis for these limitations in claims 103-105.

Claim 103 recites the limitation "wherein the reaction products form an oligosaccharide library" in lines 1-2. Claim 104 recites the limitation "wherein the products of the reaction comprise a mixture or library of oligosaccharides or polysaccharides" in lines 1-2. Claim 105 recites the limitation "wherein the products of the reaction comprise a mixture or library of oligosaccharides or polysaccharides" in lines 1-2. Claim 94 recites “A method for the preparation of glycoconjugates comprising reacting under condensing conditions involving acid or metal catalysis at least two non-protected saccharides ... in order to form a glycosidic bond between said saccharides through any free hydroxyl group position in said saccharides ...” (emphasis added). Claim 94 does not provide antecedent basis for a mixture or library of oligosaccharides or polysaccharides, or an oligosaccharide library because claim 94 does not recite a method of preparing a mixture of multiple oligosaccharides or polysaccharides. Claim 94 recites the formation of a glycosidic bond, which according the ordinary definition in the art means a single glycosidic bond is formed, and therefore the instant method for the preparation of glycoconjugates makes single products.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claims 94, 95, 98-100 and 102-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanie et al. (Solid Support Oligosaccharide Synthesis and Combinatorial Carbohydrate Libraries, 2001, p239-256, cited in PTO-892) in view of Rennhard (US Patent 3,766,165, issued 16 Oct 1973, of record) and in view of Tibor Mora et al. (US Patent 2,719,179, of record).

Kanie et al. teaches the method of making glycoconjugate libraries comprising coupling an acceptor molecule that does not carry any protecting groups (page 244, paragraph 3 and page 245, figure 12.6). Kanie et al. teaches method wherein the donor molecule has protecting groups at C2-C6 and an activating group at the C1 position using $\text{BF}_3\text{-OEt}_2$, a Lewis acid catalyst, at r.t. (page 245, figure 12.6). The definition in the art of a protected group is "Temporary chemical transformation of a reactive group into a group that does not react under conditions where the non-protected group

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reacts.” (definition of protection of a reactive group, IUPAC Gold Book, cited in PTO-892). An activating group at the C1 position does not transform the reactive C1 position into a group that does not react under conditions where the non-transformed group reacts, therefore an activating group is not a protecting group and a saccharide bearing a C1 activating group is non-protected at the C1 position. Kanie et al. teaches isolating the specific reaction products by adsorbing the products onto a column, washing to remove byproducts, and eluting from the column (page 245, paragraph 2). Kanie et al. teaches the coupling at the different hydroxyl groups of a sugar monomers, Glc, Gal, Man, Xyl, GlcNAc, GalNAc, Fuc, GlcA, and NANA, and provides guidance for the multiplicity resulting from coupling at each site (page 241, paragraph 3).

Kanie et al. does not specifically teach the method of preparing glycoconjugates wherein two non-protected saccharides are reacted (instant claim 94). Kanie et al. does not specifically teach the method of preparing glycoconjugates wherein the reaction further comprises an alcohol (instant claim 99). Kanie et al. does not specifically teach the method wherein the reaction products do not contain anhydro products or contain an amount of anhydro products which do not cause bitter taste or undesired color to the reaction products, wherein said anhydro products are levoglucosan and/or dehydrated products (instant claim 102).

Rennhard teaches it is well known in the art that saccharide polymers may be prepared by heating a saccharide in the presence of acid catalysis and references Tibor Mora et al., US Patent 2,719,179 (column 2, lines 65-72). Rennhard teaches the addition of a sorbitol, a polyol alcohol, to so as to improve the properties of the product (column 3, lines 50-55).

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Tibor Mora et al. teaches the well known method of preparing saccharide polymers by heating a saccharide in the presence of acid catalysis uses the acid catalyst hydrochloric acid and forms glycosidic bonds between non-protected saccharides through any free hydroxyl group position (column 3, lines 5-6 and 35-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Kanie et al. in view of Rennhard and in view of Tibor Mora et al. All of Kanie et al., Rennhard, and Tibor Mora et al. are drawn to the field of condensing polysaccharides. One of ordinary skill in the art would be motivated to combine Kanie et al. in view of Rennhard and in view of Tibor Mora et al. because Kanie et al. provides guidance for creating the multiplicity of polysaccharides resulting from coupling at each hydroxyl site and Rennhard teaches it is well known in the art that saccharide polymers may be prepared by heating a non-protected saccharide in the presence of acid catalysis to create such a multiplicity of polysaccharides. In so far as the instant invention is enable to make a polysaccharides with a well known or specific and substantial utility, Kanie et al. in view of Rennhard and in view of Tibor Mora et al. renders such a method of making obvious.

Kanie et al., Rennhard and Tibor Mora et al. are silent as to the formation of anhydro products. Rennhard teaches the improvement of Rennhard improves the process so as to not impart unnatural colorations to the product (Rennhard column 3, lines 40-45). As defined by Applicant, the formation of anhydro products causes undesired color in the product. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions

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that are newly cited or is identical to the process instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Conclusion

No claim is found to be allowable.

This Office Action details new grounds of rejection not necessitated by Applicant's Amendment. Accordingly, this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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